protein, 23 KD protein, 16 KD prot in, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof, said process comprising the steps of:

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transforming a host cell with a vector to form a transformed cell, said vector comprising a nucleic acid molecule encoding one of said majorly abundant secreted extracellular products; and

culturing said transformed cell to thereby produce said majorly abundant secreted extracellular product.

C8

25. The process of claim 24 which includes the additional step of recovering said majorly abundant secreted extracellular product that is produced by culturing of said transformed cell.

Remarks

The Applicants would like to thank Examiner Canella for her time and courtesy during the recent telephone conference held on October 16, 2002. During the October 2002 telephone conference the Applicants' representative and Dr. Canella discussed amendments to the remaining rejected claims in the present case. Specifically, amendments to claims 1, 4, 6, 9, 11 and 17 were discussed. Dependent claim 4, depends from claim 1 and dependent claim 9 depends from claim 6. Therefore, amendments to their independent base claims have been made, which, if allowed will render the rejections of any claims depending therefrom moot, claims 1 and 6 have been amended and claims 4 and 9 have not.

The reaming rejection of record are based on two cited references Horwitz (US 5,108,745) and Kapoor et al. (US 5,330,754) (herein after Horwitz and Kapoor respectively). Horwitz discloses intracellular pathogen vaccines generally, but does not disclose intracellular pathogen vaccines made using the specific major secreted extracelullar proteins claimed in the present application. However, Kapoor discloses Mycobacterium tuberculosis proteins having the molecular weights 12 kD, 14kD and 71 kD. Therefore, the Examiner has maintained her rejections of record as to claims 1, 4, 6, 9, 11, 17 all of which specifically recite these proteins. The Applicant has argued that Kapoor does not disclose secreted proteins having these molecular weights. In response the Examiner has correctly pointed out that the claims as pending at the time of her last office action recited "majorly abundant xtracellular products." This limitation

does not discriminat betwe n s cret d and non-secreted extracellular products. Therefore, the Applicants have amended independent claims 1, 6, 11, 17 to include the limitation "majorly abundant secreted xtracellular products." Support for this amendment can be found throughout the specification. The Examiner's attention is specifically drawn to page 18 at lines 9-14 and page 22 at lines 5-8.

The Applicants respectfully assert that by limiting the "major extracellular products" to "secreted" products that the Examiner's final rejection has been traversed and that claims 1-28, as presently amended are now in condition for allowance. The Applicants have attached a copy of the complete claim set as they believe the Examiner has allowed for convenience should the Examiner wish to review them.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changed made."**

No additional fees are seen as being necessary in connection for this amendment. However, the Examiner is authorized to charge any additional fees or credit any overpayment to Deposit Account 50-1901.

If any issues remain, the Examiner is urged to contact the undersigned by telephone for a prompt resolution thereof.

Respectfully submitted,

October 16, 2002

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Marked Up Claims S t

1. A vaccinating agent for use in promoting an eff ctive immune r spons , in a mammalian host, against an infectious pathogen from the genus Mycobacterium, said vaccinating agent comprising:

at least a portion of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof; and

an adjuvant selected from the group consisting of IL-12 and MF 59.

2. The vaccinating agent of claim 1 wherein said at least one majorly abundant secreted extracellular product is M. tuberculosis 30 KD protein.

3. The vaccinating agent of claim 1 wherein said at least one majorly abundant secreted extracellular product is a mixture of M. tuberculosis 32A KD protein, 30 KD protein, and 16 KD protein.

6. A method for immunizing a mammalian host against an infectious pathogen of the genus Mycobacterium, said method comprising the steps of:

providing a vaccinating agent comprising at least a portion of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof, and ad adjuvant selected from the group consisting of IL-12 and MF 59; and

introducing said vaccinating agent into said mammalian host to induce an effective immune response to subsequent infection by said infectious pathogen.

7. The method of claim 6 wherein said at least one majorly abundant secreted extracellular product is M. tuberculosis 30 KD protein.

8. The method of claim 6 wherein said at least one majorly abundant secreted extracllular product is a mixture of M. tuberculosis 32A KD protein, 30 KD protein and 16 KD protein.

11. A vaccinating ag nt for use in promoting an effectiv immune respons , in a mammalian host, against an infectious pathogen from th g nus Mycobacterium, said vaccinating agent comprising:

at least one immunodominant epitope of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein, and respective analogs, homologs, and subunits thereof.

12. The vaccinating agent of claim 11 wherein said at least one majorly abundant secreted extracellular product is M. tuberculosis 30 KD protein.

14. An immunodiagnositc agent for use in promoting a detectable immune response in a mammalian host identifying an infectious pathogen from the genus Mycobacterium, said immunodiagnostic agent comprising:

at least one immunodominant epitope of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof.

15. The immunodiagnostic agent of claim 14 wherein said at least one majorly abundant secreted extracellular product is M. tuberculosis 30 KD protein.

17. A method of immunizing a mammalian host against an infectious pathogen of the genus Mycobacterium, said method comprising the steps of:

providing at least one immunodominant epitope of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof; and

introducing said at least one immunodominant epitope to said mammalian host to induce an effective immune response to subsequent infection by said infectious pathogen.

18. The method of claim 17 wherein said at least one majorly abundant secr t d xtracellular product is M. tuberculosis 30 KD protein.

20. A method for detecting the presence of an immun response in a mammal against a pathogen of the genus Mycobacterium, said method comprising the steps of:

providing at least one immunodominant epitope of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof;

administering said at least one immunodominant epitope to said mammal; and

measuring the resultant immune response.

21. The method of claim 20 wherein said at least one majorly abundant secreted extracellular product is M. tuberculosis 30 KD protein.

23. A process for producing a majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof, said process comprising the steps of:

transforming a host cell with a vector to form a transformed cell, said vector comprising a nucleic acid molecule encoding one of said majorly abundant secreted extracellular products; and

culturing said transformed cell to thereby produce said majorly abundant secreted extracellular product.

25. The process of claim 24 which includes the additional step of recovering said majorly abundant secreted extracellular product that is produced by culturing of said transformed cell.

Claims as Allowed and Ready for Issuanc

1. A vaccinating agent for use in promoting an effective immune response, in a mammalian host, against an inf ctious pathogen from the genus Mycobacterium, said vaccinating agent comprising:

at least a portion of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof; and

an adjuvant selected from the group consisting of IL-12 and MF 59.

2. The vaccinating agent of claim 1 wherein said at least one majorly abundant secreted extracellular product is M. tuberculosis 30 KD protein.

3. The vaccinating agent of claim 1 wherein said at least one majorly abundant secreted extracellular product is a mixture of M. tuberculosis 32A KD protein, 30 KD protein, and 16 KD protein.

4. The vaccinating agent of claim 1 wherein said adjuvant is IL-12.

5. The vaccinating agent of claim 1 wherein said adjuvant is a mixture of IL-12 and MF 59.

6. A method for immunizing a mammalian host against an infectious pathogen of the genus Mycobacterium, said method comprising the steps of:

providing a vaccinating agent comprising at least a portion of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof, and ad adjuvant selected from the group consisting of IL-12 and MF 59; and

introducing said vaccinating agent into said mammalian host to induce an effective immune response to subsequent infection by said infectious pathogen.

7. The method of claim 6 wherein said at least one majorly abundant secreted extracellular product is M. tuberculosis 30 KD protein.

8. The method of claim 6 wh rein said at least one majorly abundant secreted xtracllular product is a mixture of M. tub rculosis 32A KD protein, 30 KD protein and 16 KD prot in.

9. The method of claim 6 wherein said adjuvant is IL-12.

10. The method of claim 6 wherein said adjuvant is a mixture of IL-12 and MF 59.

11. A vaccinating agent for use in promoting an effective immune response, in a mammalian host, against an infectious pathogen from the genus Mycobacterium, said vaccinating agent comprising:

at least one immunodominant epitope of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein, and respective analogs, homologs, and subunits thereof.

12. The vaccinating agent of claim 11 wherein said at least one majorly abundant secreted extracellular product is M. tuberculosis 30 KD protein.

14. An immunodiagnositc agent for use in promoting a detectable immune response in a mammalian host identifying an infectious pathogen from the genus Mycobacterium, said immunodiagnostic agent comprising:

at least one immunodominant epitope of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof.

13. The vaccinating agent of claim 12 wherein siad at least one immunodominant epitope is selected from the group consisting of M. tuberculosis 32A KD protein subunits having the amino acid sequences

Peptide Sequence	Seq. ID No.
W D I N T P A F E W Y D Q S G	106

P	A	F	E	W	Y	D	Q	S	G	L	S	V	V	M	107
P	V	G	G	Q	S	S	F	Y	S	D	W	Y	Q	P	110
G	C	Q	T	Y	K	W	E	T	F	L	T	S	E	L	114
K	W	E	T	F	L	T	S	E	L	P	G	W	L	Q	115
A	N	R	H	V	K	P	T	G	S	A	V	V	G	L	118
A	V	V	G	L	S	M	A	A	S	S	A	L	T	L	120
S	A	L	T	L	A	I	Y	H	P	Q	Q	F	V	Y	122
A	I	Y	H	P	Q	Q	F	V	Y	A	G	A	M	S	123
Q	Q	F	V	Y	A	G	A	M	S	G	L	L	D	P	124
G	L	L	D	P	S	Q	A	M	G	P	T	L	I	G	126
S	Q	A	M	G	P	T	L	I	G	L	A	M	G	D	127
N	D	P	L	L	N	V	G	K	L	I	A	N	N	T	134
N	V	G	K	L	I	A	N	N	T	R	V	W	V	Y	135
I	A	N	N	T	R	V	W	V	Y	C	G	N	G	K	136

and respective analogs, homologs, and subunits thereof including single or multiple amino acid substitutions, deletions, insertions, and inversions.

15. The immunodiagnostic agent of claim 14 wherein said at least one majorly abundant secreted extracellular product is M. tuberculosis 30 KD protein.

16. The immunodiagnostic agent of claim 15 wherein said at least one immunodominant epitope is selected from the group consisting of M. tubercuolsis 32 KD protein subunits having the amino acid sequences

Peptide Sequence															**Seq. ID No.**
W	D	I	N	T	P	A	F	E	W	Y	D	Q	S	G	106
P	A	F	E	W	Y	D	Q	S	G	L	S	V	V	M	107
P	V	G	G	Q	S	S	F	Y	S	D	W	Y	Q	P	110
G	C	Q	T	Y	K	W	E	T	F	L	T	S	E	L	114

K	W	E	T	F	L	T	S	E	L	P	G	W	L	Q	115
A	N	R	H	V	K	P	T	G	S	A	V	V	G	L	118
A	V	V	G	L	S	M	A	A	S	S	A	L	T	L	120
S	A	L	T	L	A	I	Y	H	P	Q	Q	F	V	Y	122
A	I	Y	H	P	Q	Q	F	V	Y	A	G	A	M	S	123
Q	Q	F	V	Y	A	G	A	M	S	G	L	L	D	P	124
G	L	L	D	P	S	Q	A	M	G	P	T	L	I	G	126
S	Q	A	M	G	P	T	L	I	G	L	A	M	G	D	127
N	D	P	L	L	N	V	G	K	L	I	A	N	N	T	134
N	V	G	K	L	I	A	N	N	T	R	V	W	V	Y	135
I	A	N	N	T	R	V	W	V	Y	C	G	N	G	K	136

and respective analogs, homologs, and subunits thereof including single or multiple amino acid substitutions, deletions, insertions, and inversions.

17. A method of immunizing a mammalian host against an infectious pathogen of the genus Mycobacterium, said method comprising the steps of:

providing at least one immunodominant epitope of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof; and

introducing said at least one immunodominant epitope to said mammalian host to induce an effective immune response to subsequent infection by said infectious pathogen.

18. The method of claim 17 wherein said at least one majorly abundant secreted extracellular product is M. tuberculosis 30 KD protein.

19 The method of claim 18 wherein said at least on immunodominant epitope is selected from the group consisting of M. tuberculosis 32A KD protein subunits having the amino acid sequences

Peptide Sequence															Seq. ID No.
W	D	I	N	T	P	A	F	E	W	Y	D	Q	S	G	106
P	A	F	E	W	Y	D	Q	S	G	L	S	V	V	M	107
P	V	G	G	Q	S	S	F	Y	S	D	W	Y	Q	P	110
G	C	Q	T	Y	K	W	E	T	F	L	T	S	E	L	114
K	W	E	T	F	L	T	S	E	L	P	G	W	L	Q	115
A	N	R	H	V	K	P	T	G	S	A	V	V	G	L	118
A	V	V	G	L	S	M	A	A	S	S	A	L	T	L	120
S	A	L	T	L	A	I	Y	H	P	Q	Q	F	V	Y	122
A	I	Y	H	P	Q	Q	F	V	Y	A	G	A	M	S	123
Q	Q	F	V	Y	A	G	A	M	S	G	L	L	D	P	124
G	L	L	D	P	S	Q	A	M	G	P	T	L	I	G	126
S	Q	A	M	G	P	T	L	I	G	L	A	M	G	D	127
N	D	P	L	L	N	V	G	K	L	I	A	N	N	T	134
N	V	G	K	L	I	A	N	N	T	R	V	W	V	Y	135
I	A	N	N	T	R	V	W	V	Y	C	G	N	G	K	136

and respective analogs, homolgos, and subunits thereof including single or multiple amino acid substitutions, deletions, insertions, and inversions.

20. A method for detecting the presence of an immune response in a mammal against a pathogen of the genus Mycobacterium, said method comprising the steps of:

providing at least one immunodominant epitope of at least one majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof;

administering said at least one immunodominant epitope to said mammal; and

measuring the resultant immun response.

21. The m thod of claim 20 wherein said at least one majorly abundant secret d xtracellular product is M. tuberculosis 30 KD protein.

22. The method of claim 21 wherein said at least one immunodominant epitope is selected from the group consisting of M. tuberculosis 32A KD protein subunits having the amino acid sequences

Peptide Sequence	Seq. ID No.
W D I N T P A F E W Y D Q S G	106
P A F E W Y D Q S G L S V V M	107
P V G G Q S S F Y S D W Y Q P	110
G C Q T Y K W E T F L T S E L	114
K W E T F L T S E L P G W L Q	115
A N R H V K P T G S A V V G L	118
A V V G L S M A A S S A L T L	120
S A L T L A I Y H P Q Q F V Y	122
A I Y H P Q Q F V Y A G A M S	123
Q Q F V Y A G A M S G L L D P	124
G L L D P S Q A M G P T L I G	126
S Q A M G P T L I G L A M G D	127
N D P L L N V G K L I A N N T	134
N V G K L I A N N T R V W V Y	135
I A N N T R V W V Y C G N G K	136

and respective analogs, homolgos, and subunits thereof including single or multiple amino acid substitutions, deletions, insertions, and inversions.

23. A process for producing a majorly abundant secreted extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD

protein, 23 KD protein, 16 KD prot in, 14 KD prot in, 12 KD protein and respective analogs, homologs, and subunits thereof, said process comprising the steps of:

transforming a host cell with a vector to form a transformed cell, said vector comprising a nucleic acid molecule encoding one of said majorly abundant secreted extracellular products; and

culturing said transformed cell to thereby produce said majorly abundant secreted extracellular product.

24. The process of claim 23 wherein said nucleic acid molecule encodes for the 30 KD M. tuberculosis protein.

25. The process of claim 24 which includes the additional step of recovering said majorly abundant secreted extracellular product that is produced by culturing of said transformed cell.

26. The process of claim 24 wherein said vector comprises pSMT3 having a nucleic acid molecule comprising SEQ ID NO 36.

27. The process of claim 24 wherein said host cell is M. smegmatis or M. vaccae.

28. The process of claim 24 wherein said transformed cell is cultured at a temperature of 28°C.